

### THE 35 U.S.C. §112, SECOND PARAGRAPH REJECTIONS

The Examiner has maintained the rejection of claim 12 under 35 U.S.C. §112, second paragraph, stating that "[t]he material elements upon which applicant relies (*i.e.*, OP-1, OP-2, OP-3, and BMP2-6) are not recited in the rejected claim(s)." May 12, 1999 Office action at page 2, paragraph 3.

In order to expedite prosecution and allowance of the present application, Applicants have amended as suggested by the Examiner. Claim 12, as amended herein, now recite the specific osteogenic proteins and bone morphogenic proteins known in the art at the time of filing of the present patent application. Applicants submit that amended claim 12 clearly identifies the material elements upon which Applicants rely. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claim 12 under 35 U.S.C. §112, second paragraph.

The Examiner has additionally maintained the rejection of claims 3 and 4 under 35 U.S.C. §112, second paragraph, stating that while the claims recite a C-terminal cysteine domain "it is unclear whether the C-terminal seven cysteine domain or some portion thereof is intended." May 12, 1999 Office action at page 2, paragraph 4.

In order to expedite prosecution and allowance of the present application, Applicants have amended claims 3 and 4 to specify that the "C-terminal cysteine domain" is the "C-terminal *seven* cysteine domain." Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 3 and 4 under 35 U.S.C. §112, second paragraph.

### THE 35 U.S.C. §103(A) REJECTION

The Examiner has maintained the rejection of claims 1-4, 6-10, 12-17, 24, 28, and 32 under 35 U.S.C. §103(a) as being unpatentably obvious over **Glassock** (V), and **Brenner** (U) in view of **Kuberasampath** (BB).

The Examiner stated at page 3 of the May 12, 1999 Office action:

Both Glassock et al. and Brenner et al. provide both a suggestion and motivation to administer anti-inflammatory therapy to a mammal in, or at risk of, chronic renal failure. See the last Office action at page 10-11. Glassock et al. also teaches that glomerular filtration rate is reduced because of infiltration of the capillaries by inflammatory cells... Kuberasampath et al. teach a method of immunosuppression with OP-1. ...One of

ordinary skill in the art would have a reasonable expectation that immunosuppression with OP-i (*sic*) would reduce the infiltration of the capillaries by inflammatory cells and glomerular filtration rate would increase.

Applicants submit again that, for the reasons provided in the May 6, 1997 Amendment and Response, the Examiner has failed to establish the required *prima facie* case of obviousness because (i) the cited references fail to provide the suggestion or motivation to modify the reference or to combine reference teachings; (ii) the cited references fail to provide a reasonable expectation of success; and (iii) the cited references fail teach or suggest all the claim limitations.

However, Applicants have amended the pending claims in order to expedite prosecution and allowance of the present application, without prejudice to the prosecution of claims of similar or greater scope in this or a subsequent related application. As amended herein, the claims are limited to mammals afflicted with chronic diabetic nephropathy, diabetic glomerulopathy, diabetic renal hypertrophy, hypertensive nephrosclerosis, hypertensive glomerulosclerosis, chronic glomerulonephritis, hereditary nephritis, renal dysplasia, glomerular hypertrophy, tubular hypertrophy, glomerulosclerosis, or tubulointerstitial sclerosis. Applicants respectfully submits that a skilled artisan would not use an anti-inflammatory therapy to treat chronic renal failure cause by nonimmune, noninflammatory conditions such as hypertension and diabetes. Accordingly, Applicants request reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a).

## CONCLUSION

On the basis of the foregoing amendments and remarks, Applicants respectfully submit that the pending claims are in condition for allowance. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

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Respectfully submitted,



Ivor R. Elrifi, Reg. No. 39,529

Michel Morency, Limited Recognition

Shelby J. Walker, Reg. No. 45,192

Attorneys for Applicants

c/o MINTZ, LEVIN, COHN, FERRIS,  
GLOVSKY AND POPEO, P.C.

One Financial Center

Boston, Massachusetts 02111

Tel: (617) 542-6000

Fax: (617) 542-2241

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